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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,622	12/12/2001	Paul F. Laeseke	960296.98636	5043
27114	7590	09/22/2004	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE, SUITE 2040 MILWAUKEE, WI 53202-4497			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,622

Applicant(s)

LAESEKE ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 9 and 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed May 28, 2004. The Examiner acknowledges that no amendments to the claims have been made by way of said amendment. Claims 5-8 and 10 are currently pending. Claims 1-4, 9 and 11-20 stand withdrawn from consideration without prejudice.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 5-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman et al. ('033) in view of Lennox (137).

Moorman et al. teaches a modular biopsy and track coagulation needle apparatus for treating the liver. The apparatus includes an introducer shaft **10** that is a hollow, electrically conductive tube. The introducer shaft **10** may be formed of a nonconductive hollow tube or of a conductive hollow tube that is covered by an outer insulating covering **17** such that an exposed first end of the shaft forms an electrically conductive surface. A biopsy needle **30** including a sampling means is fit in the introducer shaft to be guided thereby (Fig. 7). After a biopsy sample is taken using the biopsy needle **30**, the biopsy needle is withdrawn and a conductive stylet **35** is inserted into the introducer shaft. The stylet has a blunt distal end (col. 11, lines 48-50) forming a monopolar

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electrode **41** and is supported by the introducer shaft. The shaft portion of the conductive stylet includes a center conductor **55** surrounded by an outer insulating covering **60** in order to provide an insulated conductor. The conductive stylet is used as the modular needle apparatus is withdrawn from the patient in order to cauterize and coagulate the biopsy track using microwave energy in order to prevent tumor seeding, hemorrhage and bile leakage (col. 12, lines 12-48). The introducer needle may also be used in RF ablation procedures (col. 16, lines 49-58). Moorman et al. teach all of the limitations of the claims except that a large area electrode is adapted to contact the patient, that the conductive surface is in part formed by a conductive stylet, and that a temperature sensor is disposed on the electrically conductive surface.

Lennox teaches a medical device for temperature controlled RF coagulation and cauterization of liver tissue. The device includes a conductive stylet (figs. 1-6 and 9) having an insulated section **39** and an exposed, distal electrically conductive surface **28,35**. A large area electrode **8** is adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the cauterizing and coagulating electrical source with the electrically conductive surface through the patient. A temperature sensor **29,36** is disposed at the electrically conductive surface **28,35** in order to provide an indirect means of measuring and controlling the temperature of the tissue surrounding the electrode, so as to prevent excessive tissue damage.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to withdraw a biopsy needle from an introducer shaft similar to that of Moorman et al. after a biopsy sample is taken and to then insert a conductive stylet similar to that of Lennox into the introducer shaft in order to cauterize

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and coagulate the biopsy track within the liver as the introducer shaft is withdrawn from the patient, so as to prevent tumor seeding, hemorrhage and bile leakage, while providing an indirect means of measuring and controlling the temperature of the tissue surrounding the electrically conductive surface, so as to prevent excessive tissue damage.

Response to Arguments

4. Applicant's arguments with respect to claims 5-8 and 10 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Wood ('007) is not valid prior art under 35 USC 103(a) because the disclosure of the Wood application is not fully supported by the 60/330,298 provisional application on which the Wood application relies for the benefit of an earlier filing date. This argument is persuasive. Applicant further contends that the combination of the Wood and Moorman references would not be suggested to one of ordinary skill in the art because Wood and Moorman deal with radically different ablation technologies. These arguments are moot in view of the new grounds of rejection citing Moorman and Lennox set forth hereinabove.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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September 17, 2004